

Application No.: 10/550,297
Filing Date: September 21, 2005

REMARKS

Claims 21-35 stand rejected. Claims 1-20 have been previously canceled. Claims 21, 22, 24, 25, 27, and 34 are hereby amended. The amendments add no new matter. Thus, Claims 21-35 are presented for consideration and further examination in view of the following remarks.

Objection to Claim 27

The Examiner rejected dependent Claim 27 for referencing a material under the trademark “Teflon.” Applicant has amended Claim 27 to instead recite “a fluoropolymer material.” Thus, Applicant respectfully submits that the objection to Claim 27 has been overcome.

Rejections of Claims 21-28 and 31-35 under 35 U.S.C. § 102(b)

The Examiner rejected Claims 21-28 and 31-35 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,851,000 (Gupta). The Examiner also rejected dependent Claims 29 and 30 under 35 U.S.C. § 103(a) as being unpatentable over Gupta in view of U.S. Publication No. 2001/0039450 (Pavcnik et al.). With respect to the anticipation rejection of independent Claim 21, Applicant respectfully submits that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *See M.P.E.P. § 2131.*

As a preliminary matter, Applicant notes that the Examiner has interpreted the term “animal aortic valve” as recited in Claim 21 to mean an aortic valve that may be implanted in an animal. For clarification, Applicant has amended Claim 21 to instead recite “an aortic valve obtained from an animal.” Applicant has also amended dependent Claims 21, 22, 24, 25, and 34 accordingly.

Amended Claim 21 also recites, among other limitations, “an intraparietal reinforcement device comprising a rod implanted in [a] tubular wall of said aortic valve, the rod penetrating the thickness of the tubular outer wall of said aortic valve.” The Examiner has taken the position that the term “intraparietal... device” refers to a device which “may be located inside the parameters created by the walls of an organ,” and has cited the Gupta reference as disclosing the claimed “intraparietal reinforcement device.” Applicant respectfully disagrees.

Application No.: 10/550,297
Filing Date: September 21, 2005

Gupta discloses a tricuspid valve body which is constructed over a stent and sutured to the stent. (Col. 4 ll. 27-35). The stent includes parabolic scallops and an annular base ring, as well as features to allow movement between the scallops and the base. (Abstract). The parabolic scallops “taken together form a right cylinder of the *inside diameter* of the valve.” (Abstract (emphasis added)). Thus, the Gupta stent is disposed within the lumen of the valve body. Accordingly, Applicant respectfully submits that the Gupta stent is an *intraluminal* device, and not an intraparietal device as asserted by the Examiner. Further, the Gupta stent does not “penetrat[e] the thickness of [a] tubular outer wall of [an] aortic valve,” as also recited in independent Claim 21.

During patent examination, the claims must be given their broadest reasonable construction ‘in light of the specification as it would be interpreted by one of ordinary skill in the art.’” See M.P.E.P. § 2111 (quoting *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). Applicant respectfully submits that the Examiner has chosen an interpretation of the term intraparietal which is not consistent with the specification and the understanding of one skilled in the art. Under the Examiner’s interpretation, the term “intraparietal” would encompass purely “intraluminal” devices such as the devices disclosed in Gupta. However, this interpretation is inconsistent with the specification and the understanding of one skilled in the art.

With respect to the specification, the specification discusses the drawbacks associated with stented valves in the first paragraph on page 2 of the English translation submitted with the application. As stated in this paragraph, “due to the fact that the biological prosthesis that comprises this rigid ring as a stent is placed in the natural orifice, the space that is available for the replacement valve is reduced relative to the original human valve by the surface area of the circumference that is occupied by the stent. Consequently, the pressure gradient in the replacement valve is artificially increased by the presence of the stent.” In other words, intraluminal devices reduce the diameter of the orifice, resulting in an increased pressure gradient in the replacement valve relative to the natural valve.

The specification further states the claimed devices “prevent the above-mentioned drawbacks of the current means” and “use maximum surface area and available volume for their primary function.” (See last paragraph on page 3 of the English translation submitted with the application through top of page 4 of the English translation submitted with the application). The

Application No.: 10/550,297
Filing Date: September 21, 2005

specification further states that with the claimed devices “the pressure gradient in the replacement valve is, because of the increased available surface area, more comparable to the preliminary natural state.” (See third full paragraph on page 4 of the English translation submitted with the application). Likewise the specification states “the space available for the replacement valve is similar to that of the original human valve because of the absence of a bulky rigid structure like the conventional stent. Consequently, the pressure gradient in the replacement valve is also similar to its natural value, instead of being artificially increased by the presence of a stent.” (See second full paragraph on page 10 of the English translation submitted with the application). Finally the specification also provides that the claimed devices use “a maximum of the surface area and of the volume available” (See last paragraph on page 11 of the English translation submitted with the application). This language further points out that the claimed devices are not intraluminal devices which reduce the diameter of the orifice, resulting in an increased pressure gradient in the replacement valve relative to the natural valve.

Furthermore, one of skill in the art would understand the term “intraparietal” to mean “within the wall of an organ,” and not “inside the parameters created by the walls of an organ,” a definition which would encompass a purely intraluminal device. Applicants previously submitted definitions from Dorlands Illustrated Medical Dictionary with the Amendment Accompanying Request for Continued Examination filed Feb. 19, 2008. These definitions demonstrate that those skilled in the art understand the term “intraparietal” to mean “within the wall of an organ.”

In view of the foregoing, Applicant respectfully submit that the specification and understanding of those skilled in the art demonstrate that the terminology “intraparietal” does not encompass purely intraluminal devices such as the devices disclosed in Gupta. Accordingly, Applicant respectfully submits that Gupta fails to disclose at least “an intraparietal reinforcement device comprising a rod implanted in [a] tubular wall of said aortic valve, the rod penetrating the thickness of the tubular outer wall of said aortic valve,” as recited in independent Claim 21. The applied prior art of record does not cure this deficiency in the Gupta reference. Accordingly, because Gupta does not disclose each and every element of Claim 21, Applicant respectfully submits that the rejection of independent Claim 21 has been overcome.

Application No.: 10/550,297
Filing Date: September 21, 2005

Claims 22-35 depend, directly or indirectly, from Claim 21 and, thus, are patentable for at least the same reasons that Claim 21 is patentable over the applied art. Therefore, allowance of Claims 21-35 is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
11/814,155	INTRAPARIETAL REINFORCING DEVICE FOR BIOLOGICAL CARDIAC PROSTHESIS AND REINFORCED BIOLOGICAL HEART VALVE PROSTHESIS	July 17, 2007
11/775,043	REINFORCEMENT DEVICE FOR A BIOLOGICAL VALVE AND REINFORCED BIOLOGICAL VALVE	July 9, 2007

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

Application No.: 10/550,297
Filing Date: September 21, 2005

Any remarks in support of patentability of one claim should not be imputed to any other claim in this or a related application, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on solely that portion; rather, patentability must rest on each claim taken as a whole. Applicant has not presented arguments concerning whether the applied references can be properly combined in view of the clearly missing elements noted above, and Applicant reserves the right to later contest whether a proper reason exists to combine these references.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art discloses or teaches, even if not expressly discussed herein. Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter.

The undersigned has made a good faith effort to respond to all of the noted rejections and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if an issue requires clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve any such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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